DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-702/S-039

Pfizer Inc., US Agent for
Pfizer Ireland Pharmaceuticals
Attention: Madeleine M. Jester
Director, US Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Jester:

Please refer to your supplemental new drug application dated September 30, 2003, received October 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (Atorvastatin calcium) tablets.

We acknowledge receipt of your submissions dated July 16, 26, 28 (email), and 30 (email), 2004.

This supplemental New Drug Application provides for new indications, based on the results of the Anglo-Scandinavian Cardiovascular Outcomes Trial Lipid Lowering Arm (ASCOT-LLA), for the use of atorvastatin in adult patients without clinically evident coronary heart disease (but with multiple risk factors for coronary heart disease such as age $\geq$ 55 years, smoking, hypertension, low HDL-C or a family history of early coronary heart disease), to reduce the risk of myocardial infarction, and to reduce the risk for revascularization procedures and angina. In addition, this supplemental application provides for changes to the CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE and ADVERSE EVENTS sections of the LIPITOR package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We note your commitment to submit the full study report for ASCOT, the parent trial for ASCOT-LLA, within one year of completion or termination of ASCOT.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 30, 2004)(copy enclosed).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-702/S-039." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Margaret Simoneau, M.S. R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Eric Colman
7/30/04 11:55:44 AM
Eric Colman for David Orloff